In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-1450V

Filed: November 17, 2023

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VAHAN ELOYAN,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* *

Elizabeth Muldowney, Sands Anderson PC, Richmond, VA, for Petitioner
Michael Lang, U.S. Department of Justice, Washington, DC, for Respondent

DECISION ON ENTITLEMENT[1]

Oler, Special Master:

On September 21, 2018, Vahan Eloyan ("Petitioner" or "Mr. Eloyan") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[2] (the "Vaccine Act" or "Program"). The petition alleges that Mr. Eloyan developed Transverse Myelitis ("TM") as a result of the flu vaccine and the tetanus, diphtheria, acellular pertussis ("Tdap") vaccine he received on December 14, 2015. Pet. at 1, ECF No. 1.

[1] Because this Decision contains a reasoned explanation for the action in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Upon review of the evidence submitted in this case, I find that Petitioner has not preponderantly demonstrated that he suffers from TM. The petition is accordingly dismissed.

I. Procedural History

Mr. Eloyan filed his petition on September 21, 2018. Pet. at 1. He filed evidence in support of his claim on September 26, 2018 (Exs. 1-19) and on July 29, 2019 (Exs. 23-28). Respondent filed his Rule 4(c) Report on January 17, 2020, disputing that Petitioner developed TM and recommending that the case be dismissed. Resp't's Rep. at 17-18, 20, ECF No. 26.

After that, Petitioner submitted expert reports from neurologist Dr. Salvatore Napoli. Exs. 29, 51. Respondent countered with expert reports from neurologist Dr. Brian Callaghan (Ex. A), immunologist Dr. Ross Kedl (Ex. C), and neuroradiologist Dr. William Zucconi (Ex. E).

After Petitioner filed Dr. Napoli's second expert report, he requested that I conduct a Rule 5 conference and discuss my preliminary views of the case. Accordingly, on November 10, 2021, I met with counsel for both sides via telephone. During this session, I informed the parties that I found Drs. Callaghan and Zucconi, Respondent's experts, to be persuasive regarding Petitioner's diagnosis, specifically that Petitioner does not have TM and instead likely has a cervical spondylotic myelopathy ("CSM"). *See* Rule 5 Order, dated November 10, 2021; ECF No. 52. I provided specific and detailed reasons for this opinion. *Id.* At the conclusion of the conference, I informed the parties that I did not believe Petitioner had a viable path forward in the successful prosecution of his petition. Accordingly, I recommended that he dismiss his claim. *Id.* Ms. Muldowney requested time to speak with her client; I ordered that Petitioner file a status report in 45 days indicating how he would like to proceed. *Id.* at 2.

On December 27, 2021, Petitioner filed a status report requesting that I schedule his case for an entitlement hearing. ECF No. 53. After receiving input from the parties on mutually agreeable dates, I scheduled the hearing for November 14-16, 2023. Scheduling Order dated March 9, 2022. The parties filed pre-hearing briefs on October 6 and October 27, 2023. ECF Nos. 63, 69. I held an entitlement hearing via Zoom on November 15, 2023, where I heard testimony from Dr. Napoli, Dr. Callaghan, Dr. Zucconi, and Dr. Kedl.

At the conclusion of the hearing, I told the parties that in my view, preponderant evidence supports the diagnosis of cervical spondylotic myelopathy, and not TM. I further stated that I would reduce this finding to writing.

II. Applicable Law

A. Petitioner's Burden in Vaccine Program Cases

Under the Vaccine Act, when a petitioner suffers an alleged injury that is not listed in the Vaccine Injury Table, a petitioner may demonstrate that he suffered an "off-Table" injury. § 11(c)(1)(C)(ii).

In attempting to establish entitlement to a Vaccine Program award of compensation for an off-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioner establish by preponderant evidence that the vaccination he received caused his injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278.

Under the first prong of *Althen*, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Proof that the proffered medical theory is reasonable, plausible, or possible does not satisfy a petitioner's burden. *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359-60 (Fed. Cir. 2019).

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano, v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1325-26 (Fed. Cir. 2006)). However, special masters are "entitled to require some indicia of reliability to support the assertion of the expert witness." *Boatmon*, 941 F.3d at 1360, *quoting Moberly*, 592 F.3d at 1324. Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Hum. Servs.*, 121 Fed. Cl. 230, 245 (2015), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017); *see also Hock v. Sec'y of Health & Hum. Servs.*, No. 17-168V, 2020 U.S. Claims LEXIS 2202 at *52 (Fed. Cl. Spec. Mstr. Sept. 30, 2020).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause-and-effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"). As with expert testimony offered to establish a theory of causation, the opinions or

diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record. *Hibbard v. Sec'y of Health & Hum. Servs*., 100 Fed. Cl. 742, 749 (2011), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Hum. Servs*., No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id*. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id*. at 1352; *Shapiro v. Sec'y of Health & Hum. Servs*., 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem*., 503 F. App'x 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs*., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Evidence

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are generally trustworthy because they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions," where "accuracy has an extra premium." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378 (Fed. Cir. 2021) citing *Cucuras*, 993 F.2d at 1528. This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825 at *2 (Fed.

Cl. Spec. Mstr. Apr. 10, 2013), *claim den.*, 2020 WL 5641872 (Fed. Cl. Spec. Mstr. Aug. 26, 2020), *rev. den.*, 152 Fed. Cl. 782 (2021), *rev'd and remanded*, 34 F.4th 1350 (Fed. Cir. 2022).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475 at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony -- especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also *Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475 at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825 at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611 at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document every thing reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *LaLonde v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*,

617 F.3d 1328, 1339 (Fed. Cir. 2010) (*citing Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora. *Daubert* factors are employed by judges to exclude evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted").

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Id.* at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations").

D. Consideration of Medical Literature

Although this decision discusses some but not all of the medical literature in detail, I reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Hum. Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

III. Analysis

Because Petitioner does not allege an injury listed on the Vaccine Injury Table, his claim is classified as "off-Table." As noted above, to prevail on an "off-Table" claim, Petitioner must

prove by preponderant evidence that he suffered an injury and that this injury was caused by the vaccination at issue. *See Capizzano*, 440 F.3d at 1320.

Petitioner's medical history is not in dispute and is detailed in the pre-hearing briefs presented by both sides, as well as in each of the expert reports. Notably, Petitioner's past medical history is significant for cerebral palsy; however, Petitioner was active and lived independently at the time of vaccination. I have not summarized Petitioner's entire medical history, but instead discuss pertinent points in the analysis below.

A. Petitioner Has Not Carried His Burden of Proof

1. Acute Transverse Myelitis and Cervical Spondylotic Myelopathy

Transverse means "acting, lying, or being across."[3] Myelitis simply refers to inflammation of the spinal cord.[4] Accordingly, TM is a "myelitis in which the functional effect of the lesions spans the width of the entire cord at a given level."[5] TM is a heterogeneous group of inflammatory disorders of the spinal cord "resulting in motor, sensory, and autonomic dysfunction." Transverse Myelitis Consortium Working Group, *Proposed diagnostic criteria and nosology of acute transverse myelitis*, 59 NEUROLOGY 499-505, 500 (2002); (filed as Ex. A1) (hereinafter "AAN Criteria"). TM "is characterized clinically by acutely or subacutely developing symptoms and signs of neurologic dysfunction…" *Id.* at 499. The American Academy of Neurology ("AAN") Criteria were created by neurologists with expertise in spinal cord disease to aid clinicians in evaluating patients with possible acute transverse myelitis.

Dr. Zucconi defined as spondylosis as a term that refers to "structural changes that occur in the spine secondary to disc degeneration." Ex. E ("Zucconi Rep.") at 11. These changes include disc bulging, herniation, and bone overgrowth (spurring). *Id.* These processes can result in narrowing of the spinal cord and the neural foramen, which in turn can cause myelopathy[6] and radiculopathy. *Id.* Cervical spondylotic myelopathy is likely when the anterior-posterior diameter of the spinal canal is less than 10mm. Zucconi Rep. at 11. Unsteady gait, neck pain, and hand weakness are common symptoms that are consistent with a cervical spondylotic myelopathy.

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[3] *Transverse*, MERRIAM-WEBSTER.COM, www.merriam-webster.com/dictionary/transverse (last visited Nov. 16, 2023).

[4] DORLAND'S MEDICAL DICTIONARY ONLINE, www.dorlandsonline.com/dorland/definition?id=32680 (last visited Nov. 16, 2023) ("DORLAND'S").

[5] DORLAND'S, www.dorlandsonline.com/dorland/definition?id=91212&searchterm=transverse+myelitis (last visited Nov. 16, 2023).

[6] Myelopathy is "any of various functional disturbances or pathologic changes in the spinal cord, often referring to nonspecific lesions in contrast to the inflammatory lesions of myelitis." DORLAND'S, www.dorlandsonline.com/dorland/definition?id=28172 (last visited Nov. 16, 2023).

2. There is not Preponderant Evidence that Petitioner Suffers from TM

As a threshold matter, a petitioner must establish he suffers from the condition for which he seeks compensation. *Broekelschen*, 618 F.3d at 1346. "The function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner]'s injury.'" *Andreu v. Sec'y of Health & Hum. Servs*., 569 F.3d 1367, 1382 (Fed. Cir. 2009) (quoting *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)). "Although the Vaccine Act does not require absolute precision, it does require the petitioner to establish an injury – the Act specifically creates a claim for compensation for 'vaccine-related injury or death.'" *Stillwell v. Sec'y of Health & Hum. Servs*., 118 Fed. Cl. 47, 56 (2014) (quoting 42 U.S.C. § 300aa-11(c)). Accordingly, the Federal Circuit has concluded that it is "appropriate for the special master to first determine what injury, if any, [is] supported by the evidence presented in the record" before applying a causation analysis pursuant to *Althen v. Secretary of Health & Human Services, 418 F.3d 1274 (Fed. Cir. 2005). Lombardi v. Sec'y of Health & Hum. Servs*., 656 F.3d 1343, 1351-53 (Fed. Cir. 2011).

For the reasons discussed below, I find that Petitioner has not presented preponderant evidence that he suffers from TM. As this issue is dispositive,[7] I have not analyzed the *Althen* prongs.

The AAN Working Group lists the following inclusion criteria that support an acute TM diagnosis:

- Development of sensory, motor, or autonomic dysfunction attributable to the spinal cord
- Bilateral signs and/or symptoms (though not necessarily symmetric)
- Clearly defined sensory level
- Exclusion of extra-axial compressive etiology by neuroimaging (MRI or myelography; CT of spine not adequate)
- Inflammation within the spinal cord demonstrated by CSF pleocytosis or elevated IgG index or gadolinium enhancement. If none of the inflammatory criteria is met at symptom onset, repeat MRI and lumbar puncture evaluation between 2 and 7 d following symptom onset meet criteria
- Progression to nadir between 4 h and 21 d following the onset of symptoms (if patient awakens with symptoms, symptoms must become more pronounced from point of awakening)

AAN Criteria at 500.

Petitioner does not meet two of these criteria: he has not excluded a compressive etiology and he did not reach nadir between four hours and 21 days after the onset of his condition.

[7] Petitioner did not present evidence that vaccination caused or significantly aggravated his cord compression.

a. Compressive Etiology

Dr. Zucconi reviewed Petitioner's imaging studies both in his expert report and at the entitlement hearing. He opined that these images are consistent with a compressive myelopathy. Zucconi Rep. at 5. The presence of a compressive etiology eliminates TM as a diagnosis. AAN Criteria at 500.

Petitioner had an initial MRI of the cervical spine on May 26, 2016, approximately six months after vaccination. Ex. 7 at 659-60. The MRI shows "narrowing of the cervical spinal canal with superimposed moderate disc degeneration at the C3-C4 level." Zucconi Rep. at 5. There is also disc bulging and endplate spurring; and further, there is no fluid surrounding the spinal cord at the C3-C4 level. *Id*. Dr. Zucconi noted that spinal cord edema extends above and below the level of compression from C2-C3 to C5. *Id*. Although Dr. Napoli testified that the presence of inflammation both upstream and downstream from the compressed disc means that compression alone cannot explain the MRI findings, this testimony was unpersuasive.[8] Dr. Zucconi testified that the compression of Petitioner's cord at this level was sufficient to push the spinal fluid both above and below the C3-C4 level, because the fluid had no place else to go. He further testified that he sees this frequently in cases of spinal cord compression. Dr. Callaghan agreed, testifying that this is very typical. Dr. Zucconi described that cervical spondylotic myelopathy is likely when the anterior-posterior diameter of the spinal canal is less than 10mm; Petitioner's was between 7.5-8.0mm. *Id*. at 11.With respect to this initial MRI, Dr. Zucconi opined that "[t]hese findings are diagnostic of spondylotic compressive myelopathy and spinal cord injury." *Id*. at 5.

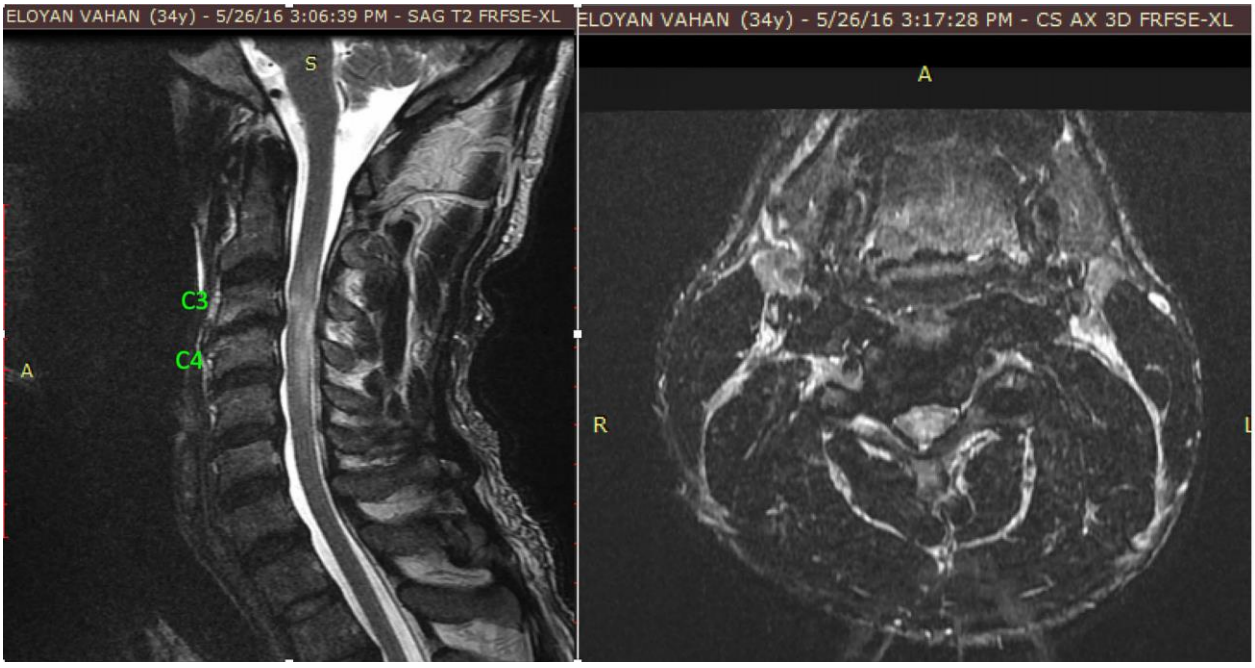

Figure 1: 5/26/16 MRI showing severe spinal stenosis, cord deformity and abnormal signal entered at the C3-4 disc level. Zucconi Rep. at 6.

[8] I have credited Dr. Zucconi's opinion over that of Dr. Napoli because Dr. Zucconi, unlike Dr. Napoli, is a board certified radiologist with a certificate of added qualification in neuroradiology. Zucconi Rep.at 1. He practices exclusively as a neuroradiologist and has done so for approximately 15 years. *Id.*

Petitioner had another MRI of the cervical spine on July 8, 2016, about one and one half months after the previous study. Ex. 3 at 8. Dr. Zucconi testified that this MRI was essential unchanged from the MRI on May 26, 2016, indicating that there has been no healing or improvement in Petitioner's condition. Dr. Zucconi opined this is what he would expect to see in a case of cervical spondylotic myelopathy.

Petitioner had an MRI of the cervical spine on October 7, 2016. Ex. 3 at 7. According to Dr. Zucconi, "the degree of cord compression and spinal stenosis has not changed," however, the degree of enhancement has progressed, indicating there is an ongoing insult. Zucconi Rep. at 9-10. This is despite the fact that Petitioner underwent a five day course of plasmapheresis and IV Solumedrol beginning on July 12, 2016. Ex. 11 at 34. Dr. Zucconi opined that Petitioner's progression on imaging is consistent with a cord compression, and would be expected if the injury is not alleviated.

Ultimately, a multi-disciplinary team at UCSF determined that Petitioner was suffering from spinal cord compression. Ex. 16 at 6. On January 8, 2018, Petitioner underwent a cervical laminoplasty.[9] *Id.* at 7. The next day, the medical record notes that he "feels better, the numbness in his toes is improved." *Id.* Petitioner had his first follow up after surgery on May 28, 2019. Ex. 46 at 1. The record documents that Petitioner had made improvements. "Prior to surgery, he had pain and numbness in his arms left worse than right and now just in his hands. Also, he was unable to walk prior to surgery. He can now walk 20-30 feet with the assistance of his caregivers." *Id.* The fact that Petitioner was evaluated by a team of physicians at UCSF, one of the world's most prestigious medical treatment centers with a top neurology program, and that this team concluded Petitioner suffered from cord compression and not TM is a significant point. The fact that surgery alleviated some of Petitioner's symptoms is further compelling evidence that TM is not his correct diagnosis. Treatment for TM was ineffective and Petitioner continued to deteriorate after receiving plasmapheresis and IV Solumedrol, which are "appropriate treatments for transverse myelitis." Ex. A ("Callaghan Rep.") at 5.[10]

In weighing evidence, special masters are expected to consider the views of treating doctors. *Capizzano*, 440 F.3d at 1326. The views of treating doctors about the appropriate diagnosis are often persuasive because the doctors have direct experience with the patient whom they are diagnosing. *See McCulloch v. Sec'y of Health & Hum. Servs.*, No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015).

Although several of Petitioner's treating physicians diagnosed him with TM, the Court is not obliged to adopt the same view. *See* 42 U.S.C. §§ 300aa-13(b)(1) (providing that "[a]ny such

[9] Laminoplasty: "incision completely through one lamina of a vertebral arch with creation of a trough in the contralateral lamina; the vertebral arch is then opened like a door with the trough acting as a hinge; performed to relieve compression of the spinal cord or nerve roots." DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=27536 (last visited Nov. 17, 2023).

[10] Dr. Callaghan testified at the entitlement hearing that Petitioner did have some improvement after steroids. He testified that this is expected because steroids make people feel better. However, the improvement was temporary, and Petitioner continued to deteriorate after treatment.

diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). The ultimate conclusion from the interdisciplinary team at UCSF, and the subsequent successful surgery, carries significant weight in my analysis.

There is preponderant evidence that Petitioner's MRIs demonstrate the presence of a compressive etiology, which excludes a TM diagnosis under the AAN Criteria.

b. Onset to Nadir

Mr. Eloyan received the flu and Tdap vaccines on December 14, 2015. Ex. 17 at 2. Petitioner contends that his medical condition changed at the end of January.[11] On January 25, 2016, Petitioner reported hand weakness, balance problems, as well as neck and lower back pain to his chiropractor. Ex. 5 at 10. The tingling and weakness in Petitioner's lower extremities increased slowly over time and spread to his upper extremities. Ex. 4 at 2. On May 26, 2016, Petitioner was admitted to the hospital because his "ambulatory status was dramatically reduced." Ex. 7 at 562. Dr. Stewart offered Petitioner a wheelchair, but he declined. *Id*. On May 31, 2016, he was unable to walk. *Id*. at 330. Petitioner was wheelchair bound at a medical appointment in July of 2016 and August of 2016. Ex. 3 at 2; Ex. 11 at 184. A note from September 7, 2016, documents that Petitioner had improved after his hospitalization, although he was not back to baseline. Ex. 11 at 198.

An entry from one of Petitioner's treating physicians at UCSF summarized his clinical course.

> The patient reports symptom onset in January 2016, when he began experiencing a gradual progressive onset of weakness and numbness in one of his arms and legs. … Around the same time he was also having difficulty with balance, and his parents report that he was falling. … Between January 2016 and April 2016 the patient reports that the frequency of his falls was increasing and his grip strength was decreasing but he was still ambulatory and got married. He was having trouble walking up the stairs at his parents[']house. Then he reports spread of symptoms to the other side of his body, both leg[s] and hand[s]. Again, all slowly progressive. He reports that his symptoms eventually progressed to "complete paralysis" of his arms and legs. … Between September 2016 and present the patient reports minimal improvement in his symptoms.

Ex. 16 at 983-84. These records suggest that nadir occurred around early September 2016. This finding is in accord with Dr. Callaghan's opinion expressed in his expert report and at the

[11] However, Petitioner's chiropractic record from December 7, 2015, where he reported balance issues, hand weakness, and neck and low back pain suggests that his condition began before vaccination. Ex. 5 at 10. Accordingly, I have assumed, but do not conclude, that Petitioner's condition began on January 25, 2016, for the purpose of discussing the onset to nadir of his condition.

entitlement hearing. *See, e.g.,* Callaghan Rep. at 4 (noting "progression of symptoms over at least 10 months from December to September.").

The progression of Petitioner's symptoms is well outside that outlined in the AAN Criteria and is inconsistent with a diagnosis of TM. Kelley et al., describe that "patients with transverse myelitis characteristically reach a nadir of deficit within 2 weeks." Kelley et al., *Compressive Myelopathy Mimicking Transverse Myelitis*, 16 THE NEUROLOGIST 2, 120-22 (2010) (filed as Ex. E-10). Dr. Callaghan testified at the entitlement hearing that months and months of progression are completely incompatible with TM. I agree with this assessment.

I and other special masters have found that a lengthy period of time between onset of symptoms and nadir suggests that a Petitioner does not have acute TM. *Goodwin v. Sec'y of Health & Hum. Servs.*, No. 16-1676V, 2023 WL 7924657, at *30 (Fed. Cl. Spec. Mstr. Oct. 23, 2023) (concluding that an interval of 41 days from onset to nadir was not consistent with acute TM); *Murray v. Sec'y of Health & Hum. Servs.*, No. 19-1976, 2022 WL 17853378, at *9 (Fed. Cl. Spec. Mstr. Nov. 30, 2022) (finding a six month plus progression of neurologic problems from onset to nadir is not consistent with TM); *Pearson v. Sec'y of Health & Hum. Servs.*, No. 16-09V, 2019 WL 3852633, at *15 (Fed. Cl. Spec. Mstr. July 31, 2019) (noting that "most TM sufferers advance from onset of symptoms to maximum deficit within weeks, days, or even hours.").

c. Oligoclonal Bands

Petitioner had three oligoclonal bands in his CSF that were not present in the serum. Ex. 7 at 652. Dr. Napoli testified at the entitlement hearing that the presence of oligoclonal bands made this case a "slam dunk" in favor of a TM diagnosis because there should be zero bands if Petitioner had a cord compression. Dr. Callaghan disagreed and noted that the presence of oligoclonal bands is not included in the diagnostic criteria for TM. Further, he testified that the test's threshold to report the result as positive was four bands; therefore, this was a negative result. In addition, Dr. Schubert, one of Petitioner's treating physicians stated the following:

> The presence of oligoclonal bands in the CSF is of unclear significance in this case, as these have been reported in a wide variety of conditions including structural CNS lesions and can not be used in isolation to exclude a structural etiology as the driver of pathology (Cohen and Steiner. JAMA Neurology 2010. Cerebrospinal Fluid Oligoclonal IgG Bands in Patients With Spinal Arteriovenous Malformation and Structural Central Nervous System Lesions).

Ex. 16 at 989. Accordingly, I do not find the presence of three oligoclonal bands in Petitioner's CSF to be determinative or even especially persuasive evidence in support of a TM diagnosis.

Ultimately, the fact that Petitioner's presentation did not meet the AAN Criteria for acute TM constitutes compelling evidence that TM is not his correct diagnosis. His MRIs demonstrated that he suffered from spinal cord compression. The slow progressive course of his condition over at least eight months is not "acute" and is well in excess of the 21-day outer limit delineated in the AAN Criteria. His lack of imaging improvement after plasma exchange, and his notable improvement after cervical laminoplasty provide further strong support against a diagnosis of TM.

Petitioner has my sympathy for the many years of suffering he has experienced as a result of his condition. However, my decision must be based on the evidence in the record.

IV. Conclusion

Upon careful evaluation of all the evidence submitted in this matter, including the medical records, the affidavits and testimony, as well as the experts' opinions and medical literature, I conclude that Petitioner has not shown by preponderant evidence that he is entitled to compensation under the Vaccine Act. **His petition is therefore DISMISSED. The clerk shall enter judgment accordingly.**[12]

IT IS SO ORDERED.

s/ Katherine E. Oler
Katherine E. Oler
Special Master

[12] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by each filing (either jointly or separately) a notice renouncing their right to seek review.